UNCLAS SECTION 01 OF 02 WELLINGTON 000119

SIPDIS

STATE PASS USTR FOR BWEISEL AND DKATZ
STATE PASS FDA FOR OFFICE OF INTERNATIONAL
PROGRAMS/RUSSELL CAMPBELL
STATE FOR EAP/ANP AND EB/TPP/BTA/ANA
COMMERCE FOR 4530/ITA/MAC/AP/OSAO/GPAINE

SENSITIVE

E.O. 12356: N/A
TAGS: ETRD NZ
SUBJECT: NEW ZEALAND AND AUSTRALIA DELAY STARTUP OF JOINT REGULATORY AGENCY

REF: 04 WELLINGTON 596

¶1. (SBU) Summary: New Zealand and Australia have agreed to delay the startup of a joint agency to regulate therapeutic products in both countries, after encountering difficulty in lining up political backing for legislation necessary to set up the agency. In New Zealand's case, that difficulty partly arises from the coming national election. An adviser to New Zealand's health minister fears a delay until after this year's election could doom the trans-Tasman effort and force New Zealand to upgrade its own regulatory regime, at a much higher cost. Meanwhile, the industry believes itself to be in a stronger position to influence the government to address its concerns about the agency's fees and certification requirements. The New Zealand government -- often criticized by business for having a tin ear to its concerns -- may have to pay heed to industry this time. End summary.

¶2. (U) The trans-Tasman agency had been scheduled for launch July 1 and now could be delayed until July 1, 2006, although it might start earlier. It would regulate prescription pharmaceuticals as well as other therapeutic goods, including medical devices and health-care products that have gone virtually unregulated in New Zealand (reftel).

¶3. (U) In New Zealand, industry's support for the joint agency has been conditional. U.S. manufacturers of medical devices and complementary medicines want the agency's costs to be addressed, contending that the current plan to charge full cost-recovery fees would harm their sales and put some of their distributors out of business in New Zealand, where low operational costs have allowed for generally lower prices than in Australia. Pharmaceutical companies want assurances that the agency will not be used as an excuse to ban direct-to-consumer advertising, which some firms have used successfully in New Zealand. Such advertising is prohibited in Australia and personally opposed by New Zealand Minister of Health Annette King.

¶4. (U) Medical-device representatives also fear higher costs if the agency follows through with plans to exclusively conduct all conformity assessments -- audits of manufacturers and testing of products to ensure they meet relevant standards. Such plans would give the agency monopolistic powers, accompanied by monopolistic costs, the representatives say. The agency also presumably would follow the Australian practice of accepting CE, or European, certification. The plans leave unresolved how the agency would handle products having U.S. Food and Drug Administration certification but not CE certification.

¶5. (SBU) With New Zealand's Labour government lacking sufficient strength in Parliament to pass the implementing legislation alone, it is turning to the industry for help in recruiting support from the ranks of opposition parties. On January 24 and February 10, Minister King made a pitch for help at meetings with representatives of the pharmaceutical, medical devices, over-the-counter medicines and complementary medicines sectors. The representatives termed the meetings the "most positive" they have had with the government since their discussions on the agency began in 1998. With the government now acknowledging that it needs the industry's backing, the representatives hope to take a tougher line in pushing their concerns, whose resolution would allow them to fully support the agency.

¶6. (SBU) Meanwhile, an adviser to Minister King said that the delay in the agency's startup could jeopardize its future, especially if legislation is not approved before the next national elections, which must be held by September. For example, Labour's ability to form another coalition government may depend on support from the Green Party, which adamantly opposes the agency because of fears about the loss of sovereignty and the effect on consumers' health choices and access to dietary supplements.

¶7. (SBU) Unable to agree on a joint statement on the delay, the New Zealand and Australian governments issued separate statements. The statements were released February 9 in Canberra and February 10 in Wellington. According to Minister King's

office, Australian Parliamentary Secretary for Health Christopher Pyne opposed Minister King's desire to state that the agency's governance and accountability arrangements would be included in the legislation rather than in regulations alone. (Minister King did not mention the issue in her statement.)

¶8. (SBU) Comment: The dispute is emblematic of the difficulties both governments face in attempting to harmonize their economies, a goal of the Closer Economic Relations arrangement begun in ¶1983. The issue of "sovereignty" is extremely sensitive for the relatively small New Zealand, just one-fifth the population of Australia. Hence, Minister King would like the joint agency's governance arrangements enshrined in legislation to address this sensitivity. (Australian officials have griped privately that New Zealand will have an equal number of representatives on the agency's board, while Australia would shoulder most of the startup costs.)

¶9. (SBU) The New Zealand government is also reportedly nervous that Australia might become impatient and look elsewhere for a partner. Australia, which is said to be seeking to position itself as a hub for regulatory services in the Pacific region, has held discussions with Canada on a possible joint regulatory agency.

SWINDELLS